Boston Children's Hospital

Date: Wednesday, April 29, 2020 10:37:55 AM Print Close

Title: Sample Reliance on Another IRB

General Information

1 * **Protocol Title:**
Sample Reliance on Another IRB

Maximum of 230 characters may be entered.

2 **Full Title - If protocol title exceeds the 230 characters limited from field above, enter full title here. Otherwise, leave blank.**
Sample Reliance on Another IRB

3 * **Provide a brief summary (in lay terms) of the research protocol.**
Brief summary

4 * **Principal Investigator (PI):** PI Test

4.1 * **To serve as a PI you must qualify under one of the following eligibility requirements. (Residents, interns, fellows and postdoctoral candidates are not permitted to be PIs). Please select the appropriate category that applies to you.**
Physicians, Dentists and Psychologists credentialed through the hospital with the BCH medical staff registrar as an active medical staff member and having an appointment of Instructor or higher at Harvard Medical School.

If Other patient services professionals:

4.1.1 **Research is part of your scope of employment responsibility and not to meet a training or degree requirement. Please explain how this research falls within the scope of your responsibilities at the hospital.**

4.1.2 **You have training and experience and confirmed clinical research competencies. Please explain your training and experience in clinical research.**

4.1.3 **Are you employed at Children's as a nurse or do you have nursing credentials through Boston Children's Hospital?**
Please note if this is checked yes, in accordance with the policies of the Nursing Department your protocol will be sent to the Nursing department for both scientific review and departmental sign off.
○ Yes ○ No

5 * **Is the person who will be primarily responsible for conducting the study at BCH different from the PI?**
○ Yes ● **No**

If YES:

5.1 **Please add the person(s) who will be primarily responsible for conducting the study.**

Name	Appointment with Children's Hospital?
There are no items to display	

6 **Has the PI, or if question #5 was YES has that person, previously served as a PI of a protocol involving interaction/intervention with human subjects at CHB?**
● **Yes** ○ No

7 * **Type Of Submission:**
○ New Research Activity
○ **New Research Activity Limited to Secondary* Use of Biological Material and Data

- ○ Establishment of Human Biological Specimen Repository/ Data Registry (only) – repositories/registries are defined as a prospective collections of specimens or data that are processed, stored, distributed to multiple investigators for use in research.
- ○ Request for Exemption
- ○ Individual Patient Expanded Access
- ○ Humanitarian Use Device (HUD)
- ● **Reliance on Another IRB**
- ○ Projects that lack immediate plans for involvement with human subjects, their data and/or their specimens (i.e.training grants)

*** Use this form only if:*
1) specimens/data are not identifiable or
2) specimens/data are identifiable but recorded by PI in de-identified format or meet the waiver of HIPAA authorization criteria listed below All other uses of secondary specimens/data must be submitted on a new research activity form.

** Secondary means the tissue or data will be or was collected for a primary or initial purpose other than the research (i.e data from medical records, tissue from pathology)*

Waiver of HIPAA authorization (all criteria must be met)
• The proposed use of this data/document/record/specimen presents no more than minimal risk to the privacy of individuals
•The research could not practicably be conducted without the waiver of HIPAA authorization
• The research could not practicably be conducted without access to and use of protected health information with identifiers
• Waiving HIPAA authorization will not adversely affect the subject's rights or welfare

This form may not be selected if the study involves interaction/intervention with subjects in order to obtain tissue/data specifically for this research.

8 * **Is this protocol related to child health (including perinatology, prenatal assessments, childhood antecedents of adult disease, and long-term follow up of pediatric disorders)?**

● **Yes** ○ No

9 * **Is this protocol related to cancer (primarily concerning malignancies, oncology patients, or involving use of malignant tumors)?**

○ Yes ● **No**

Note: If YES, your protocol will require review by the Dana Farber IRB instead.
For details, see: IRB Policy 3.12, 'Reliance Agreements'

10 * **Will this protocol utilize any of the services of the ETU (Experimental Therapeutics Unit)?**
Please select "No" for the following types of submission:
1. Request for Exemption
2. Projects that lack immediate plans for involvement with human subjects, their data and/or their specimens (i.e.training grants)

○ Yes ● **No**

These services include:

- *Use of space on the ETU or research space at Waltham*
- *Nursing assistance at above sites*
- *Off-site nursing and/or research coordinator services provided through ETU*
- *Specimen collection or processing, sample storage and preparation for shipping*
- *Assistance from nutritional Metabolic Phenotyping Core (preparation of research meals, analysis of food records, etc.)*
- *Use of specialist equipment located on the ETU (3DMD camera, DXA, pQCT, V-max, etc.)*

Note: If YES, your protocol will be routed for Harvard Catalyst CRC Protocol Review PRIOR to BCH IRB review. For details, see: Institutional Centers for Clinical and Translational Research (ICCTR)

11 * **Does this protocol include COVID-related research with subjects diagnosed or suspected with COVID19 that meet any of the following criteria?**
• Use of discard clinical samples (nasal swabs, blood, etc.)
• Collection of clinical samples from patients (blood, nasal swabs, sputum, urine, stool etc.)

• Collection of demographic and clinical information at time of patient encounter
• Interaction or intervention with patients (therapies, extra testing , interviews) while in the hospital (inpatient, ambulatory, emergency department)

● **Yes** ○ No

Note: Do not check "Yes" for research limited to retrospective or prospective collection of data or surveys/interviews conducted with families and patients through non inperson encounters.

Note: If "Yes" - the scientific review will be automatically routed to a newly formed SRC committee established to conduct COVID19 research reviews. In addition you are required to obtain approval by institutional representatives who have been assigned responsibility by hospital location for prioritizing multiple requests, assuring protocols meet standards for infection control, and appropriate personnel are involved.
Please contact them early during your research planning so they can provide guidance.
Please note that the processes, capabilities, and requirements differ by site.

Investigators with proposals than span different locations should discuss their research plan with all site leads:
ED: Mark Neuman, MD
ICU and ORs: Adrienne Randolph, MD
In-patient: Benji Raby, MD
Laboratory Medicine: Orah Platt, MD and Nira Pollock, MD

If you would like to request ICCTR support please contact Andy Place, MD (Chief Medical Officer) and Cindy Williams, RN MS, NE-BC (nursing)

Title: Sample Reliance on Another IRB

Reliance on Another IRB

This protocol should be completed when Boston Children's Hospital (BCH) IRB will rely on another institution's IRB. Although another institution will provide IRB review and approval, this protocol will go through administrative review to track all research occurring at BCH/by BCH investigators and to manage any applicable ancillary (non-IRB) reviews.

1 Please check all categories which are appropriate for your research and reliance agreement.

1.1 * **BCH staff or employees will recruit, consent and/or perform research assessments at Boston Children's Hospital facilities but will rely on another IRB.**

● **Yes** ○ No

Example: A research protocol is approved at another hospital but the Boston Children's Hospital PI will recruit and consent subjects at BCH.

If YES:

1.1.1 Please indicate all research activities being conducted at BCH. Check all that apply:

- ☐ Recruitment
- ☐ Consenting
- ☐ Medical Chart/Record Review
- ☐ Identifiable Data Analysis
- ☐ Data Collection
- ☐ Other

If Other:

Please specify:

If Data Collection:

Please check all that apply:

- ☐ Conducting surveys/questionnaires
- ☐ Drug/Device intervention
- ☐ Clinical exams and medical assessments (i.e. exams, x-rays, scans, EKG, ECHO, EEG, MRIs)
- ☐ Specimen collection (for clinical testing or research)
- ☐ Other

If Other:

Please specify:

1.2 * **Subjects are enrolled in research protocols at other sites under the jurisdiction of another IRB but the facilities or resources of Boston Children's Hospital are used for one or more of the research assessments.**

● **Yes** ○ No

Example: Research subjects recruited from another site are sent to BCH for a research procedure and the BCH staff member is a co–investigator.

If YES:

1.2.1 Please specify which BCH facilities or resources will be used and for which research assessments:

1.3 * **Children's staff or employees will recruit, consent and/or perform research assessments of research subjects outside of Children's Hospital and under the jurisdiction of another IRB.**

● **Yes** ○ No

Example: A Children's investigators collaborate with a PI from another institution and agrees to travels to a community health center to conduct interviews as part of a larger study approved by another IRB.

If YES:

1.3.1 Please indicate all research activities to be conducted by Children's staff/employees outside of BCH. Check all that apply:

- ☐ Recruitment
- ☐ Consenting
- ☐ Medical Chart/Record Review
- ☐ Identifiable Data Analysis
- ☐ Data Collection
- ☐ Other

If Other:

Please specify:

If Data Collection:

Please select all that apply:

- ☐ Conducting surveys/questionnaires
- ☐ Drug/Device intervention
- ☐ Clinical exams and medical assessments (i.e. exams, x-rays, scans, EKG, ECHO, EEG, MRIs)
- ☐ Specimen collection (for clinical testing or research)
- ☐ Other

If Other:

Please specify:

1.4 * **Children's staff or employees will solely be involved in data analysis* and/or recruitment limited to reviewing data for potential subjects. Note that IRB oversight may not be required for data analysis only. Please contact the IRB Reliance Specialist for assistance BEFORE completing this application if BCH's involvement is limited to these activities.**

● **Yes** ○ No

Example:

- BCH researchers are conducting a retrospective chart review, adding BCH patient data to another site's dataset.
- BCH researchers are involved in identifiable data analysis of BCH or another site's data.
- BCH researchers review data for potential subjects to be referred to another site's researchers.

2 * **Please indicate (provide rationale) why a reliance agreement is being requested. In other words, please describe why BCH IRB should cede review and oversight to another institution's IRB.**

Justification for reliance agreement

Research Team

If the person you need to add to your protocol cannot be found using the “Add” buttons below, please send an email to CHERP Support (cherp.support@childrens.harvard.edu) requesting that the person be added to the Research Staff. CHeRP Support will need the following information:
First Name
Last Name
CHID# (if applicable)
BCH Department (if applicable)
Email Address

1 **Research Staff - Children's Hospital Employees only:**

	Last Name	First Name	Role	Editor	CC on Correspondence	Required Training Completed	CHeRP Training	Date Modified	Date Created
View	Kuniholm	Ashley	Admin Contact	yes	yes	yes	yes	12/4/2019	12/4/2019

2 **PI:** PI Test

Completed Training Courses:

Training Program	Continuing Education Description	Training Completed	Date Created
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	7/22/2018	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	7/12/2018	
Continuing Education	Continuing Education/Department Meeting	5/2/2018	
Continuing Education	Continuing Education/Department Meeting	6/13/2016	
Training Received at Another Institution		11/15/2015	
Continuing Education	Continuing Education/Department Meeting	10/26/2015	
Continuing Education	Research Protocol Case Discussions	11/15/2012	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/9/2012	5/9/2012
Continuing Education	Continuing Education/Department Meeting	9/30/2011	
CHeRP Training		12/19/2010	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/15/2009	11/8/2010
Collaborative IRB Training Initiative (CITI Behavioral)		8/2/2006	11/8/2010
Collaborative IRB Training Initiative (CITI Biomedical)		8/2/2006	11/8/2010
Collaborative IRB Training Initiative (CITI Non-Interventional)		4/11/2006	11/8/2010
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	4/5/2006	11/8/2010

Title: Sample Reliance on Another IRB

Funding Sources

1 * **Select funding category.**

○ Externally sponsored (federal, state, corporate, foundations)

- (●) **Internally sponsored**
- ( ) Externally and internally sponsored
- ( ) No sponsor
- ( ) Private Donor

1.1 If internally sponsored - select as appropriate:

- [ ] Department/ Division or Children's foundation funds
- [x] **Internal Children's Grant Award**

1.2 Enter any additional information if applicable:

1.3 If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

1.4 Please provide the name of the private donor.

Financial Disclosure

1 * **Do you or any person affiliated with the protocol have or expect to have any investment or financial relationship (examples below) with any entity that is providing funds or other support in connection with the protocol?**

( ) Yes (●) **No**

If YES:

1.1 Please select the relationships as appropriate.

- [ ] Consulting
- [ ] Payments for protocol/study design
- [ ] Protocol-related payments not included in the research agreement budget
- [ ] Stock or Options
- [ ] Honoraria
- [ ] Scientific Advisory Board Membership
- [ ] Royalties or license fees related to the protocol, or to any test article or device which will be employed in the conduct of the research under the protocol (including any royalties or license fees received through an academic institution, including Children's Hospital).
- [ ] Equipment or other laboratory support
- [ ] Other support for research unrelated to the protocol
- [ ] Support for educational or other academic or medical efforts
- [ ] Other Grants
- [ ] Other

2 * **Do you or any person affiliated with the protocol have or expect to have any proprietary interest related to the protocol, or related to any test article or device that will be employed in the protocol? Include proprietary interests that you have assigned to any entity, including any institution you have been affiliated with.**

( ) Yes (●) **No**

If YES:

2.1 Please select the proprietary interest as appropriate.

- [ ] Patent-licensed, in whole or part, to an entity providing funds for the research
- [ ] Patent-licensed, in whole or part, to another entity

☐ Other

3 * **Do you or any person affiliated with the protocol have or expect to have any advisory role, appointment, or employment with any entity that is providing funds or other support for the research to be conducted under the protocol?**

○ Yes ● **No**

If YES:

3.1 Please select as appropriate.

☐ Scientific Advisory Board Membership

☐ Other Advisory Role

☐ Officer

☐ Director

☐ Employment

☐ Other

4 * **Do you or any person affiliated with the protocol have or expect to have any financial interest, financial relationship, or position or advisory role with any other entity that may be affected by the research to be conducted under the protocol (e.g. competitor, customer, collaborator or commercial sponsor affiliate)? Include any entity that may be benefited or harmed, directly or indirectly.**

○ Yes ● **No**

5 * **Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?**

○ Yes ● **No**

6 * **The IRB prohibits special incentives in connection with clinical research, including, finder's fees, referral fees, recruitment bonuses, enrollment bonuses for reaching an accrual goal, or similar types of payments. Will you or anyone else in connection with the conduct of any research under the protocol receive money, gifts or anything of monetary value that is above and beyond the actual costs of enrollment, research conduct, and reporting of results, from the sponsor or any other entity?**

○ Yes ● **No**

7 * **Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?**

○ Yes ● **No**

8 **If any of the questions above are checked "Yes", please provide the name of the individual for whom the disclosure is made and describe in further details the disclosure. This section must include a full description of the financial relationship, including but not limited to, a detailed description, as applicable, of any test article of device involved; the advisory role or appointment; the competitor, customer, collaborator; any arrangement related to the research; and so on. Please also include actual amounts of any consulting or other monies received and the time period for which it was received. This section will not be reviewed without a full disclosure.**

9 **Upload any other pertinent documentation.**

Name	Date Last Modified	Version	Owner

There are no items to display

Title: Sample Reliance on Another IRB

Reliance Information

1 * **What type of reliance agreement is being requested?**

- ☐ Single Reliance (Reliance agreement between BCH and another institution not affiliated with a master agreement)
- ☑ **SMART IRB Master**
- ☐ Master consortium/network Reliance (other than SMART IRB)

If SMART IRB:

1.1 Please provide SMART IRB ID number.
555

1.2 Please upload a copy of the SMART IRB request here.
SMART IRB request.docx(0.01)

2 * **What Institution will be performing IRB review and serve as the IRB of record (the IRB providing review)?**
Columbia University Medical Center - FWA00002636

If Other:

2.1 Please enter the institution name.

3 **Who is Principal Investigator at site for IRB of record (the IRB providing review)?**

* **Principal Investigator's Name**
Bob
* **Principal Investigator's Email**
Loblaw

4 * **Has this protocol already been reviewed by the IRB of record (the IRB providing review)?**
● **Yes** ○ No

If YES:

4.1 What is protocol number?
RASCAL00088981

4.2 Please upload a copy of the initial approval letter.
Initial Approval Letter.docx(0.01)

4.3 Please upload a copy of the latest approval letter (if continuing review has occurred).

5 **IRB CONTACT AT INSTITUTION TO REVIEW PROTOCOL (IRB of record)**

5.1 Name
Name

5.2 Phone Number
Phone Number

5.3 Email
Email

Multi Site Information - Reliance

1 * **Is this a multi center study?**
● **Yes** ○ No

If YES:

1.1 Is Children's Hospital, Boston the lead site or coordinating center?
○ Yes ● **No**

1.2 Will data be shared between sites?
Yes

1.3 Please provide a description of the reviewing PI's oversight process to assure that relying institutions:
**** are provided timely access to approved and revised approved protocols, informed consents and recruitment materials**
**** are informed about the reviewing IRB's polices that pertain to this research**
**** provide (the reviewing PI) with any required COI management plans, required information pertaining to continuing reviews and any reportable events**
description of the reviewing PI's oversight process

Subject Information

1 Enrollment Numbers

1.1 * Specify the number of subjects enrolled by, or under the auspices of Children's Hospital, that are required to complete data analysis.
Number

1.2 If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through CHB. If not applicable, please leave blank.
Larger number

2 Special Population

- [ ] Prisoners/Incarcerated Youth (this would include children under the care of the Department of Youth Services). Consider if your target population will be or at higher risk of incarceration. If this category is chosen, you will be prompted to answer additional questions to meet federal regulations.
- [ ] Wards of the State (consider if your target population may contain wards of the state or children at risk of becoming a ward of the state (this includes foster children or any child that is in state custody))
- [x] Adults With Decisional Impairment

*__Decisional Impairment__ is defined as: *persons who have impaired ability to make decisions as a result of intellectual or mental health challenges as well as individuals who have lost capacity to make decisions because of clinical situations such as unconsciousness.*

Study Location

1. If your research is conducted in any of the following location(s) please check all that apply. If your research does not include any of these sites, please leave the questions blank.

- [x] **Adolescent Medicine**
- [ ] Adolescent Surgery
- [ ] Cardiac ICU
- [ ] Cardiac Surgery
- [ ] Infant Toddler Surgical
- [ ] Infant/Toddler Medical
- [ ] Intermediate Care Program (ICP, 11 South)
- [x] **Medical/Surgical ICU (7 South)**
- [ ] Medicine ICU (11 South)
- [ ] Neonatal ICU
- [ ] Neurology
- [ ] Oncology/Hematology
- [ ] Psychiatry
- [ ] School Age Medical
- [ ] School Age Surgical
- [ ] Sleep Study

- [ ] Solid Organ Transplant
- [ ] Stem Cell Transplant

Other CH Locations

- [x] **Cardiac Cath Lab**
- [ ] Children's Hospital Primary Care Center (CHPCC)
- [ ] Clinical and Translational Study Unit (CTSU)
- [ ] Emergency Department
- [ ] Martha Elliot Health Center (MEHC)
- [ ] MRI
- [ ] Nuclear Medicine/PET
- [ ] OR/PreOp/PACU
- [ ] Other Satellites (Lexington, Peabody, South Shore, etc.)
- [ ] Radiology

Off Premises e.g. Schools, other Hospitals, Home

- [ ] Beth Israel Deaconess
- [ ] Brigham and Women's Hospital
- [ ] Boston Medical Center
- [ ] Dana Farber Cancer Institute
- [ ] Harvard Medical School
- [ ] Harvard School of Public Health
- [ ] Subject's Homes
- [ ] Joslin Diabetes Center
- [ ] Mass Eye and Ear Infirmary
- [ ] Mass General Hospital
- [ ] MIT
- [x] **Other**
- [ ] Physician Office
- [ ] School
- [ ] Tufts – New England Medical Center

1.1 *If Other:*
Specify:
Columbia

Recruitment and Document Storage

1 * **Describe plans for recruitment at BCH, including identification of /screening for potential participants, who will be responsible for recruitment, and how and when subjects will be recruited.**
Plans for recruitment at BCH

2 * **Describe informed consent/assent/authorization procedures to be followed at BCH, including who will obtain informed consent/assent/authorization, and when and where subjects will be consented/assented.**
Informed consent/assent/authorization procedures

3 ***Where will research data, documents and subject reports be sent and stored? Check all that apply.**

- [x] Children's Hospital Medical Record
- [x] Departmental Medical Record
- [x] Separate Research Record
- [ ] Subject/family will receive results
- [ ] Sponsor, Collaborator and/or Coordinating Center
  Specify:
- [x] Medical Record at another institution, hospital, physician's office, etc.
  Specify:
  Explanation
- [x] Research Registry
  Will data include patient identifiers (name, medical record, SS #)?
  (●) **Yes** ( ) No
- [ ] Other
  Specify:

4 ***Where will the signed informed consent and assent be stored? Check all that apply.**

- [x] Children's Hospital Medical Record
- [x] Departmental Medical Record
- [x] Separate Research Record
- [x] Sponsor, Collaborator and/or Coordinating Center
- [x] Medical Record at another institution, hospital, physician's office, etc.
- [ ] Research Registry
- [ ] Not Applicable

Clinical Trials.Gov

Please answer the following information regarding ClinicalTrials.gov registration.

1 * **Into which of the following category(s) does this protocol fall (check all that apply):**

- [x] **(a) A controlled clinical investigation other than phase 1 of a drug subject to FDA regulation (requires registration). *CONTROLLED* is defined as a design to permit comparison of a test intervention with a control to provide a quantitative assessment of the drug/ effect. This can include concurrent control groups as well as non concurrent controls including historical controls or subjects as their own controls (requires registration by FDA regulations)**
- [ ] **(b)** Protocol prospectively compares a device-based intervention subject to FDA regulation against a control in human subjects (requires registration). An ***INTERVENTION*** broadly includes various techniques using the device such as, among other things device regimens and procedures, and use of prophylactic, diagnostic or therapeutic agents. This applies to studies other than a small clinical trial to determine feasibility of a device, or a clinical trial to test prototypes devices where the primary outcome measure relates to feasibility and not health outcome. **(Requires registration by FDA regulations)**
- [x] **(c) A device trial that is a pediatric post-market surveillance trial (requires registration by FDA regulation)**
- [ ] **(d)** Protocol prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. **(ICMJE requires registration)**
- [ ] **(e)** Protocol does not meet any of the criteria above (a-d) but research will be registered on clinicaltrials.gov (voluntary registration, statement optional)
- [ ] **(f)** Protocol does not meet any of the criteria above (a-d) and research will not be registered on clinicaltrials.gov

If (a), (b), (c), or (d) is checked, either FDA regulations or International Committee of Medical journal Editors (ICMJE) Guidelines *http://www.icmje.org/recommendations/browse/publishing-and-editorial-*

issues/clinical-trial-registration.html ***require that this trial be registered on a clinical trial registry. FDA requires registration on ClinicalTrials.gov site. ICMJE requires registration on one of a broader list of registries, including clinicaltrials.gov.***
For further information about required registrations you may go to:

• *http://clinicaltrials.gov/ct2/manage-recs* ***(FDA regulations)***
• *http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html* ***(ICMJE)***

Note if (a), (b) or (c) is checked, FDA regulations require that the consent form contains the following statement:

"A description of this clinical trial will be available on *http://www.ClinicalTrials.gov****, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of results. You can search this web site at anytime."***

If (d) or (e) is checked you may voluntarily choose to include the statement above. Please make the appropriate updates to the consent form accordingly.

1.1 Who will be responsible for registering the trial?

- ☐ Sponsor (if other than BCH PI/Sponsor-Investigator)
- ☐ BCH PI or Sponsor-Investigator
- ☑ **Investigator at another site**
- ☐ Other

If Other:

1.1.1 Please specify who.

1.2 If you have selected BCH PI or Sponsor-Investigator do you have a Clinical Trial registration NCT number for this study at this time?

○ Yes ○ No

If YES:

1.2.1 Please insert "NCT" number for this trial

NOTE: A valid NCT number must be included before the IRB releases final acceptance of this reliance request. If the NCT number is not included in the original submission you will need to register the trial and update this form before final acceptance is released.

Medical Expenses for Research Related Adverse Events

1 *How will the cost of reasonably foreseeable medical care in the event of a research related adverse event be covered?

- ☑ Corporate sponsor agreement
- ☑ Likely to be covered by insurance
- ☐ Philanthropic or other grant
- ☐ Foundation or Departmental Funds
- ☐ Interdepartmental arrangements
- ☐ Other
  Explain:
- ☐ Not applicable

Protected Health Information and HIPAA Authorization Information

Protected Health Information (PHI) is information acquired by Children's Hospital, including demographic information, that could reasonably identify an individual **AND**:
Relate to the past, present, or future physical or mental health, condition or treatment of an individual;
OR
Describe the past, present, or future payment for the provision of healthcare to an individual.

There are some limited situations when research protocols will not use or create protected health information. For example, educational research conducted in a school setting.

1 ***The following information is considered identifiable PHI under the Privacy Rules regulations. Indicate which of the following will be obtained.**

- [x] **Patient/Subject Name or the names of relatives, employers, or household members**
- [x] **Medical record numbers (or specimen #)**
- [ ] Address street location
- [x] **Address town or city ***
- [x] **Address state***
- [x] **Address zip code***
- [x] **Elements of Dates (except year) related to an individual. For example date of birth, admission or discharge dates, date of death, dates of procedures***
- [ ] Telephone number
- [ ] Fax Number
- [x] **Electronic mail (email) address**
- [x] **Social security number**
- [x] **Health plan beneficiary numbers**
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identification numbers and serial numbers including license plates
- [ ] Medical device identifiers and serial numbers
- [ ] Web URLs
- [ ] Internet protocol (IP) address
- [ ] Biometric identifiers (finger and voice prints)
- [ ] Full face photographic images/any comparable image/video of the face
- [ ] Any unique identifying number, characteristic or video

Please explain in more detail.

- [ ] NONE OF THE ABOVE: this protocol will not use any identifiable PHI

** These items may be included and considered a "limited data set". Use of data under the provisions of a "limited data set" require the signing of a data use agreement by the recipient (this includes researchers).*

PHI Disclosure

1 **Please check all of the categories that indicate where a research subject's PHI may be disclosed. For this purpose, "disclosure" means release, transfer, provision of access, or otherwise divulging protected health information outside the entity initially acquiring the information as specified in the protocol; most often that will be Children's Hospital Boston.**

- [x] Internal at Children's Hospital
- [x] Data Safety Monitoring Committee
- [ ] Food and Drug Administration (FDA)
- [x] Other health care providers of subject

Third Party Payers - if third parties are billed for procedures performed during research

- [x]
- [x] Sponsor of Trial
- [x] Contract Research Organization (CRO): organizations contracted to perform portions of the study (i.e., screening, data collection)
  Specify the name/organization.
  CRO name
- [ ] Collaborator
  Specify who and the location.
- [ ] Cooperative Group/Network
  Specify the name of the network/group.
- [ ] Other
  Specify who and the location.

Research Categories and Special Considerations

1 Please select the appropriate research category for your research. A primary category must be selected. A secondary category should be selected only if applicable.

* **Primary Research Categories:**

- (●) **Intervention/Trial Therapeutic (e.g. drugs, devices, comparison of therapeutic approaches, new procedures)**
- ( ) Intervention/Trial Non-Therapeutic (extra ECHO, MRI, physical exams for non-therapeutic purposes)
- ( ) Behavioral/Psychosocial Interventions/Trials
- ( ) Establishment of Specimen Repository
- ( ) Epidemiology/Observational Study – e.g. survey, case/control/data registries, cohort studies
- ( ) Quality Improvement
- ( ) Lab Specimen Studies – e.g. blood, urine, extra tissue during biopsy, genetic research
- ( ) Educational/Training – e.g. training of residents or other professional staff

Secondary Research Categories:

- ( ) Intervention/Trial Therapeutic (e.g. drugs, devices, comparison of therapeutic approaches, new procedures)
- (●) **Intervention/Trial Non-Therapeutic (extra ECHO, MRI, physical exams for non-therapeutic purposes)**
- ( ) Behavioral/Psychosocial Interventions/Trials
- ( ) Establishment of Specimen Repository
- ( ) Epidemiology/Observational Study – e.g. survey, case/control/data registries, cohort studies
- ( ) Quality Improvement
- ( ) Lab Specimen Studies – e.g. blood, urine, extra tissue during biopsy, genetic research
- ( ) Educational/Training – e.g. training of residents or other professional staff

2 Please check all of the following that apply to the proposed research AND WILL BE PERFORMED at BCH facilities.

- [x] This protocol involves the use of a drug, biologic, nutritional supplement, herbal or homeopathic medicine, medical food, medical gas, inhalation therapy, topical cream, chemical or other compound that will be administered as the object of the protocol or because it is relevant to the aims of the research protocol.
- [x] This protocol involves a device that will be used, administered, implanted, or applied to the subjects, as the object of the protocol or is relevant to the objectives of the protocol. This includes investigational devices classified as both significant risk and non significant risk as well as FDA approved/marketed devices.
- [x] This protocol involves the collection and use of material for genetic studies or creation of IPS lines as part of this current study and/or for potential genetic studies in the future.

- [x] This protocol involves the use of a placebo.
- [x] This protocol includes an imaging exam or procedure to be done in Radiology or Nuclear Medicine for research purposes. Please contact Simon Warfield (Simon.Warfield@childrens.harvard.edu) and Kristina Pelkola (Kristina.Pelkola@childrens.harvard.edu). Simon and Kristina will collect some additional information from you and coordinate the review of the information through Radiology to assure that the imaging protocol can be performed, the correct charges have been established and that Radiology will be able to accommodate the study in the imaging schedule. You will not be able to have imaging performed without this. It is imperative that you contact Simon or Kristina immediately.
- [x] This protocol requires for research purposes 1) radiological assessments and procedures that involve radiation exposure (X-ray, CT, PET scans) or 2) nuclear medicine procedures (imaging or therapeutic). (Do not check this category if these procedures and assessments will be performed as part of clinical care).**
- [x] This protocol requires for research purposes MRI scans (Do not check this category if these procedures and assessments will be performed as part of clinical care).**
- [x] This protocol involves the establishment of a human biological specimen repository. Repositories are defined as prospective collections of specimens that are processed, stored and distributed to multiple investigators for use in research.
- [x] This protocol involves the collection of a tissue removed for clinical purposes that would routinely go to pathology.
- [x] This protocol acquires fetal biospecimens (This includes specimens taken from pregnant women or acquisition of fetal tissue obtained from terminations).
  If fetal tissue from terminations are proposed please be sure to include in your protocol document or SmartForm detailed information about where it is acquired from and how it will be used. In addition, submit copy of IRB approvals from sites where the tissue was actually obtained.
- [x] This protocol recruits or perform research assessments on pregnant women evaluated through the BCH Advanced Fetal Care Center (AFCC). Please note if this is checked, the AFCC will be notified and may contact you to discuss the research.
- [x] This protocol includes an intervention with human subjects that involves either
  a) the derivation of stem cells from embryos or,
  b) the implantation of stem cells obtained from fetal tissue or embryos.
- [x] This protocol includes research that is conducted at a non US location.
  Please check this off if you are conducting international research but be aware that these questions do not apply to multi-site studies that are also multi-national.
- [x] This protocol involves collection of blood samples other than discarded specimens.
- [x] This protocol involves the use of a device that emits laser radiation.

*** This must be selected if the protocol involves imaging, regardless of where the imaging may occur.*

3 * Is there any possibility that a referral to social work will be triggered or a social work assessment/consultation will be required as a result of your use of any quality of life measure or other survey/questionnaire?

● **Yes** ○ No

If YES:

3.1 A responsible social worker must be identified before this protocol can be submitted.
Please check the following as appropriate:

3.1.1 [x] A BCH social worker has been identified to work on this project

3.1.2 [ ] A social worker from your own funding source will work with you on this project

3.2 Please address the following: What is their name? What is the expected time commitment (hours/wk)?
Name and expected time commitment.

3.3 Please upload a written agreement, signed by that social worker, stating that they are willing and available to make that time commitment.

Name	Date Last Modified	Version	Owner
Agreement.docx	4/2/2020 10:58 AM	0.01	PI Test

*NOTE: If you have questions please email: socialworkadmin@childrens.harvard.edu with the following subject line: **Social Work Involvement in Research: IRB Protocol #XXXX** to schedule a 30 minute appointment to discuss the needs related to social work involvement in your study protocol.*

Nursing/Biosafety/Gene and Cellular Therapy

1 * **Will this protocol require any of the following nursing services for any research related direct care requirements?**

● **Yes** ○ No

If YES:

1.1 Check all that apply:

- [ ] Assessment of physical/mental status of subjects
- [ ] Monitoring requirement non invasive
- [x] **Monitoring requirement invasive**
- [ ] Additional intravenous requirements
- [x] **Collection of blood and specimens**
- [x] **Frequent timed lab draws**
- [ ] Accompany patients to test areas
- [ ] Patient/family education, including self and home care
- [ ] Administration of investigational drugs and other substances
- [ ] Use of new technology/equipment in study protocol
- [ ] Symptom management/intervention
- [ ] Constant supervision
- [ ] Requirements from other services that require nursing coordinator

1.2 Specify required services.
Required services.

2 * **Does your study involve the administration of any of the following to a human research participant?**
● **Yes** ○ No

If YES:

2.1 Please check all that apply.

- [x] **Genetically-modified cells or seek to genetically modify patient tissues in vivo using recombinant or synthetic nucleic acid molecules (natural-derived or synthesized DNA or RNA)**
- [ ] A cellular or biologic product that involves complex manufacturing (e.g. cell culture or cell selection in a GLP/GMP facility, outside the operating room)
- [ ] Biological agents or material containing biological agents. Biological agents include bacteria, viruses, parasites, rickettsia, fungi, prions and toxins of biological origin regardless of pathogenicity to humans (e.g. fecal microbiota transplantations, oncolytic viruses)
- [ ] Xenotransplantation (cells, tissues or organs from a nonhuman animal source or have come into contact with nonhuman sources)

NOTE: Please note if the first or second option is checked, the protocol will be routed to a specialized institutional scientific review committee and will not be sent for your own departmental scientific reviewers.

If option *"Genetically-modified cells or seek to genetically modify patient tissues in vivo using recombinant or synthetic nucleic acid molecules (natural-derived or synthesized DNA or RNA)"* was selected, please check off as applicable for this research and answer the associated questions:

2.1.1 The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk.
● **Yes** ○ No

2.1.1.1 If Yes, please describe vector, genetic material, and delivery method and what may be known about any associated risks.
Description of vector, genetic material, and delivery method and what may be known about any associated risks.

2.1.1.2 If No, please indicate the section or location in the protocol where the vector, genetic material or delivery methodologies risks are clearly described based on previous experience in human studies.

2.1.2 The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value.
● **Yes** ○ No

2.1.2.1 If Yes, please describe the new preclinical model system of unknown and unconfirmed value.
New preclinical model system of unknown and unconfirmed value.

2.1.2.2 If No, please explain why this is not a preclinical model system of unknown and unconfirmed value.

2.1.3 The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies (IRB, IBC) to evaluate the protocol rigorously.
○ Yes ● **No**

2.1.3.1 If Yes, please describe why the possible toxicities are not widely known and may render it difficult for oversight bodies (IRB, IBC) to evaluate the protocol rigorously.

2.1.3.2 If No, please justify that the possible toxicities are widely known and oversight bodies (IRB, IBC) will be able to evaluate the protocol rigorously.

Justification.

Drugs, Biologics or Other Products

Please provide information for the drug/product that will be used, administered, or applied to the subjects as the object of the study or that is relevant to the objectives of the protocol. If there is more than one drug/product, please be sure to enter each drug/product. More than one drug/product may be entered under each category.

1 The drug/biologic/product being administered is an investigational product (not approved by the FDA)

	Generic Name	Type of Product	Manufacturer
View	generic name	Drug	manufacturer

2 The drug/biologic/product being administered is an FDA-approved agent but used outside of the FDA labeling in an unapproved dose, route of administration, population, disease, in concomitant medical use, etc.

Generic Name	Type of Product	Manufacturer
There are no items to display		

3 The drug/biologic/product being administered is FDA approved and being administered in accordance with approved labeling

Generic Name	Type of Product	Manufacturer
There are no items to display		

4 The drugs/biologics/products being administered does not fit into any of the above categories.

Generic Name	Type of Product	Manufacturer
There are no items to display		

5 The product being administered is a dietary supplement, herbal medicine, or medical food.

Product Name	Type Of Product
There are no items to display	

6 Select the individuals that can prescribe the drugs listed in this protocol.

Last Name	First Name	Employee ID
Kuniholm	Ashley	123524
Test	PI	120216

Special Considerations - Device

Provide information for the device that will be used, administered, implanted or applied to the subjects as the object of the study or that is relevant to the objectives of the protocol. If there is more than one device, please be sure to enter each device under the appropriate category. More than one device may be entered under each category.

1 Investigational Devices (devices not approved or cleared for marketing by the FDA)

	Generic Name	Trade Name	Manufacturer
View	generic name	trade name	manufacturer

2 **FDA Approved Devices that are used for a non-approved indications or in a non-approved population or devices that have been modified /altered/ edited, reconfigured/changed/combined**

Generic Name	Trade Name	Manufacturer
There are no items to display		

3 **Devices that have been approved (PMA) or Cleared (510(k)) by FDA and used in accordance with labeling**

Generic Name	Trade Name	Manufacturer
There are no items to display		

4 **Other Devices**

Generic Name	Trade Name	Manufacturer
There are no items to display		

Genetic/IPS Lines Research Technology Classification

1 * **What type of genetic technology will be used in your research? You may select more than one.**

- [x] DNA Sequencing
  - [x] Single Gene Sequencing
  - [x] Multi-gene Sequencing (either individually or on a panel)*
  - [x] Whole Exome Sequencing (WES)*
  - [x] Whole Genome Sequencing (WGS)*
- [x] Genome-wide Association Study (GWAS)*
- [x] Linkage Analysis*
- [ ] Microarray Analysis
  - [ ] Chromosomal Microarray Analysis (CMA)*
  - [ ] SNP Array
- [ ] Gene Expression/RNA Seq Analysis
- [ ] Other

If Other:
Please specify.

2 * **Will collected biological specimens (e.g. blood, tissue) be used to establish a DNA cell line?**

● **Yes** ○ No

If YES, please explain:

2.1 Why are you collecting the biological specimens to establish the DNA cell lines? Please describe.
Rationale

2.2 How do you plan on collecting these specimens?
How long

2.3 How will the DNA cell lines be used?
Use

1 * **Will family members be included in the study?**

○ Yes ● **No**

If YES:

1.1 What are the confidentiality issues that must be considered during the recruitment of family members (family members may not know an individual is sick or has a specific condition)?

1.2 Describe the proposed strategy for recruiting subjects/family members. The plan should ensure that prospective subjects are sufficiently protected from coercion or undue influence.

1.3 Describe how family members will be protected against the disclosure of medical or other personal information about themselves to other family members.

Genetic Research - Page 3

1 * **RETURN OF RESULTS TO PARTICIPANTS: Will you return any genetic results from this study, either primary research results (i.e., those pertaining to the condition under study) AND/OR incidental/secondary findings (i.e. non-paternity OR genetic results that do not pertain to the condition under study but may be important for the participant to know, e.g., the identification of risk for disease or conditions other than the one under study) to the participant? The plan to return or not to return any genetic results has to be addressed in the consent form.**

● **Yes** ○ No

If YES:

1.1 Will you return primary research results (i.e. those pertaining to the condition under study in the participant) to participants?

● **Yes** ○ No

If NO:

1.1.1 Please explain why you will not provide primary research results to participants.

If YES:

1.1.2 Will you give participants an option (opt-in or opt-out) to receive these results?

Opions?

1.2 Is there the possibility that there may be incidental/secondary findings on participants? Please note that this must be answered yes if you are performing GWAS, multi-gene sequencing, WES, WGS, linkage analysis, or microarray analysis on family members. This should also be explained in the consent form.

● **Yes** ○ No

If YES:

1.2.1 Will you return incidental/secondary genetic results that do NOT pertain to the condition under study to participants?

● **Yes** ○ No

If YES:

1.2.1.1 Please describe the types of results you will return (e.g., use the ACMG recommended gene list or other criteria)?

Types of results.

1.2.1.2 Will you give participants an option (opt-in or opt-out) to receive these results?

Options?

If NO:

1.2.1.3 Please explain why you will not provide incidental/secondary research results to participants.

2 * **RETURN OF RESULTS TO FAMILY MEMBERS: Will family members undergo genetic studies? This should also be explained in the consent form.**

● **Yes** ○ No

If YES:

2.1 Will you return primary research results (i.e. those pertaining to the condition under study in the participant) to family members?

● **Yes** ○ No

If NO:

2.1.1 Please explain why you will not provide primary research results to family members.

If YES:

2.1.2 Will you give family members an option (opt-in or opt-out) to receive these results?
Options?

2.2 Is there the possibility that there may be incidental/secondary findings on family members? Please note that this must be answered yes if you are performing GWAS, multi-gene sequencing, WES, WGS, linkage analysis, or microarray analysis on family members. This should also be explained in the consent form.

○ Yes ● **No**

If YES:

2.2.1 Will you return incidental/secondary genetic results that do NOT pertain to the condition under study to family members?

○ Yes ○ No

If YES:

2.2.1.1 Please describe the types of results you will return (e.g., use the ACMG recommended gene list or other criteria)?

2.2.1.2 Will you give family members an option (opt-in or opt-out) to receive these results?

If NO:

2.2.1.3 Please explain why you will not provide incidental/secondary research results to family members.

3 * In accordance with the Hospital's CLIA (Clinical Laboratory Improvement Amendment) license, research results of participant's laboratory tests not confirmed in a CLIA certified lab (including results of genetic testing), may not be released to the participant or to the participant's clinician for the purpose of diagnosis and/or treatment. Thus the research result/s must be confirmed in a CLIA-certified laboratory before communicating the results to the family/participant and return of results must be addressed in the consent form.
Will your genetic research be performed in a CLIA-certified lab?

● **Yes** ○ No

If NO:

3.1 Describe how you will arrange to have the test result confirmed in a CLIA-certified lab, the process for contacting the participant and/or family members, and what will be communicated to the participant and/or family members about the result and CLIA confirmation.

3.2 How will the costs of the testing in a CLIA-certified laboratory be covered? (If families are expected to cover the cost of the testing in a CLIA-certified laboratory this should be addressed in the consent document).

3.3 Specify how you will return the CLIA certified research results or incidental finding to participants and/or family members. Who will release the results? Who will be given the information (e.g. family, treating clinician)? What support will be available to the participant/family once the results are disseminated (i.e. genetic counseling)?

4 * Describe how the data will be protected from third parties, such as employers and insurance companies.
Data protection plan.

5 * Are there psychological, economic and/or social risks associated with the genetic research and the results obtained?

○ Yes ● **No**

If YES:

5.1 What are the risks and what steps will be taken to minimize or eliminate these risks?

Placebo

1 * Briefly describe the placebo (drug, device, procedure, intervention, surgery, etc.) arm used in

the study. Provide a justification for use of the placebo, including the length of subject participation in the placebo arm. Please justify why the study cannot be conducted without the use of the placebo. Your justification should address whether outcomes are subjective and how use of a placebo will address this issue, if applicable.
Description of placebo.

2 * **Describe any commonly used diagnostic/treatment approach(es) that will be withheld from subjects assigned to the placebo arm of this study. Will subjects be denied any type of treatment or diagnostics that would be considered a current standard of care?**
Commonly used diagnostic/treatment approach(es) that will be withheld.

3 * **Summarize any risks to subjects in the placebo arm consequent to not receiving active treatment for their disease or condition.**
Any risks to subjects in the placebo arm consequent to not receiving active treatment.

4 * **Summarize the potential benefits from participation in this protocol for subjects in the placebo arm.**
Potential benefits from participation in this protocol for subjects in the placebo arm.

5 **If applicable, how will the condition or disease of subjects in the placebo arm of this study be monitored compared to the monitoring associated with standard care for this disease/condition?**
How will the condition or disease of subjects in the placebo arm of this study be monitored?

6 **If applicable, what criteria will be used to determine that the participation of a subject, who may be receiving a placebo treatment, should be discontinued due to his/her worsening disease or condition?**

Imaging

1 * **Does your protocol involve any of the following radiological procedures that involve radiation exposure as part of the research protocol? (do NOT identify procedures that are part of the subject's required clinical care)**
● **Yes** ○ No

If YES:

1.1 Select all that apply:
- ☑ **X-rays**
- ☑ **Fluoroscopy / Cineradiography**
- ☑ **Computed Tomography (CT)**
- ☑ **Bone Density by X-Ray Absorptiometry (DEXA)**

If you checked any of the above:

1.1.1 Provide a description of the imaging protocol.
Imaging protocol.

1.1.2 Provide a detailed description of the radiation exposure involved in the study (i.e. how many additional x-rays, how much additional fluoroscopy time, etc.).
Detailed description of the radiation exposure involved.

1.1.3 Provide the whole body radiation exposure per procedure anticipated from the research protocol expressed in units of milliRem (mRem) or milliSieverts (mSv). This information may be obtained by contacting Safety Officer Ryan Toolin at 617-355-7298 or ryan.toolin@childrens.harvard.edu**.**
Whole body radiation exposure per procedure.

2 * **Does your protocol involve any imaging studies that do not involve radiation exposure as part of the research protocol (do NOT identify procedures that are part of the subject's required clinical care)?**
○ Yes ● **No**

If YES:

2.1 Does it involve ultrasound?
○ Yes ○ No

3 **When do you expect to begin imaging?**
when

4 **If a radiologist/nuclear medicine specialist is collaborating on this research, please specify the individual.**
Ashley Kuniholm

5 * **Does your protocol involve Nuclear Medicine Studies as part of the research protocol? (do NOT identify procedures that are part of the subject's required clinical care)**
○ Yes ● **No**

Human Biological Repository

Repositories are defined as collections of specimens that are processed, stored and distributed to multiple investigators for use in research. Answer these questions only if the establishment of a repository is part of the protocol. Storing remaining samples from the research is not considered a repository unless the purpose of storage is to make samples available to other investigators.

1 * **Enter information for each type of specimen that will be collected as part of the proposed repository and provide the pertinent information. Enter one at a time; please add additional specimens after completing the pertinent information for the selected specimen.**

	Specimen Category	Amount
View	Blood	4ml

Human Biological Repository - Identifiable Information

1 * **Will any identifiers or identifiable health information about the individual from whom the human material/tissue will be obtained be temporarily or permanently recorded with or linked to the material/tissue?**
● **Yes** ○ No

2 * **Will you retain a link to the subject's medical record in the repository so that the individual subject's health/medical information may be reviewed in the future?**
● **Yes** ○ No

3 * **Duration of storage, labeling of samples: State how long you expect to maintain the repository. Describe the acquisition, logging in, and tracking of samples. Explicitly state whether the repository will retain a key to the code linking the sample to the individual from whom the sample was obtained. Describe where the key to this code will be kept and who will have access to it. If, after obtaining identifiable tissue for a specific research goal, you plan to de-identify the remaining excess human material/tissue for further research, clarify how and when this will occur.**
Duration of storage, labeling of samples.

4 * **Process for Distribution of Tissue: Clarify the process by which other investigators may request tissue from the repository, if proposed. Describe who oversees tissue requests (e.g., an individual, group of individuals, or board), provide the process for determining the merits or acceptability of the request for tissue. Describe what materials are provided to requesting researchers. Clarify who at the repository will assess tissue requests and ensure that, where necessary, there is a current IRB-approved protocol covering the proposed research.**
Process for Distribution of Tissue.

5 * **Will samples be distributed with a unique identifier?**
● **Yes** ○ No

If YES:

Distribution of tissue that is coded but not directly identifiable is not considered human subjects research if the recipient researcher will not seek to identify the individual from whom the tissue was obtained. However, there may be limitations as to how the samples can be used depending on the informed consent document that was signed. The recipient researcher must agree in writing to never attempt to access identifiable health/medical information or to attempt to identify the subject(s) who provided the sample(s). Such coded human material/tissue may be distributed without separate, independent IRB approval once the recipient researcher signs the agreement stating that s/he will not attempt to identify human subjects from whom the samples were derived.

Provide a copy of a formal letter or form that recipient investigators will be asked to sign for such tissue distributions.

Name	Date Last Modified	Version	Owner
Recipient Investigators Agreement.docx	4/2/2020 4:56 PM	0.01	PI Test

6 * **Will subjects potentially be re-contacted by representatives of the repository?**
○ Yes ● **No**

If YES:

6.1 **Describe in detail:**
(1) reasons for re-contact;
(2) how and when re-contact would occur, or might occur, if not obligatory;
(3) how subjects will provide updated contact information, if necessary;
(4) whether an option for "no re-contact" is possible and reasonable;
(5) what research information would be released to subjects or placed in medical records;
(6) what counseling would be provided, and what notification of subject's physicians would be undertaken, if any.

Pathology Specimens

1 * **For those specimens that would routinely go to Pathology, please provide the following information for each category of specimen that will be collected.**

	Tissue Type	Amount
View	Surgical discards	3mm

Title: Sample Reliance on Another IRB

International Research

Research conducted by Children's Hospital investigators falls under the hospital's purview and guidelines even when conducted elsewhere. If research is conducted internationally, the project must also have been approved by the local equivalent of an IRB before it can receive final approval from the Children's Hospital. When there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. In most situations, the IRB requires documentation of this "local approval" before it gives its approval.

1 * **Does this research involve any research activities in the European Union or the countries of Iceland, Liechtenstein or Norway?**
● **Yes** ○ No

If YES:

1.1 **Please list the countries:**
Belgium, Liechtenstein, San Marino, Norway

1.2 **Does the study involve collection of information from or electronic monitoring of subjects in the European Union, Iceland, Liechtenstein or Norway?**
● **Yes** ○ No

1.3 **Is any data or information collected as part of the study going to be transferred or processed in the European Union Iceland, Liechtenstein or Norway?**
● **Yes** ○ No

2 * **Describe qualifications the researcher has in relevant coursework, past experience, or training to verify his/her international/cross cultural research capabilities.**
Qualifications the researcher has.

3 **If the investigator is working with local collaborators (Local Co-PI) please describe this arrangement. Please include information about the background and experience of the local collaborator as it pertains to this research protocol. Also describe the allocation of responsibility for the various research related activities.**
Describe arrangement.

4 * **Provide a description of the context of cultural norms or local laws and differences with U.S. culture with respect to research, autonomy of individuals or groups, consent procedures, recruitment techniques, age of majority, requirements for parental consent, etc. Include an explanation of what cultural considerations will be required to conduct this study.**
Context of cultural norms/laws.

5 **If this research involves a population or community with limited resources, describe how the research is responsive to the health needs and the priorities of the population or community and how any intervention or product developed, or knowledge generated will be made reasonably**

available for the benefit of that population or community.

6 * **Explain the researcher's ability to speak, read, or write the language of the potential participants. Describe the primary language(s) spoken in the community. Explain provisions for culturally appropriate recruitment and consent accommodations such as translations or involvement of native language speakers.**
Researcher's ability to speak, read, or write the language of the potential participants.

7 * **Describe if the researcher has knowledge of or expertise in the local or state or national laws that may have an impact on this research. The researcher must understand cultural or community attitudes to appreciate laws, regulations, and norms and remain in compliance with U.S. regulations for the research as well as local requirements.**
Researcher's knowledge of or expertise in the local or state or national laws

8 * **Have there been any specific issues that have been identified that may represent a difference in standard practices between the local IRB and the BCH IRB? If so please describe.**
Any specific issues that have been identified

9 * **Describe if the researcher was invited into the community. If yes, then provide documentation of the collaboration. If not, describe how the researcher will have culturally appropriate access to the community.**
Describe if the researcher was invited into the community.

10 * **Provide information about the ethics committee (IRB equivalent) or other regulatory entity conducting review of the research in the host country. Provide contact information for the local entity. If this research is US federally funded, additional documentation and inter-institutional agreements will be needed. Contact the Children's Hospital IRB office for guidance.**
Information about the ethics committee.

11 **Describe any aspects of the cultural, political or economic climate in the country where the research will be conducted which might increase the risks for participants. Describe the steps you will take to minimize these risks.**
Any aspects of the cultural, political or economic climate.

12 * **Please describe how and when the informed consent documents will be translated.**
How and when the informed consent documents will be translated.

13 **Please upload documentation of the international IRB approvals or Ethics approvals here, if available.**

Name	Date Last Modified	Version	Owner
Documentation of the international IRB approvals.docx	4/2/2020 5:00 PM	0.01	PI Test

Title: Sample Reliance on Another IRB

Blood Collections

1 **Select the method(s) of blood collection.**

- 1.1 ☑ Venipuncture
  - 1.1.1 ☑ At time of clinically indicated procedure
  - 1.1.2 ☑ At time specifically for research
- 1.2 ☑ Heel/finger/ear sticks
- 1.3 ☐ From catheter or heparin lock
- 1.4 ☐ Other

If Other:

1.4.1 **Please specify.**

2 * **How many individual samples will collected (not number of sticks)?**
1

Note: Multiple withdrawals of blood from an indwelling venous line are to be considered more than one collection.

3 * **What is the period of time the samples will be collected (please specify in weeks or if less than weeks in days)?**
1 time

4 * **Specify the total amount of blood collected in mls.**
4ml

5 * **Will research subjects be less than 16.5 kg?**
○ Yes ● **No**

If YES:

5.1 **Will the total amount of blood to be drawn from children less than 16.5 kg be more than 3mL/kg?**
○ Yes ○ No

Protocol and Consent

1 * **Upload a copy of the protocol that is submitted to/approved by the IRB of record.**

Name	Date Last Modified	Version	Owner
PROTOCOL.docx	4/2/2020 5:01 PM	0.01	PI Test

2 **Upload all consent and assent forms. If there is more than one, list the titles or categories of each form submitted (e.g. experimental, control, sub-study).Please ensure these are Word documents to allow for BCH IRB office edits.**

Name	Date Last Modified	Version	Owner
Belgian Assent.docx	4/2/2020 5:03 PM	0.01	PI Test
Belgian Consent.docx	4/2/2020 5:03 PM	0.01	PI Test
English Consent.docx	4/2/2020 5:03 PM	0.01	PI Test
Italian Assent.docx	4/2/2020 5:03 PM	0.01	PI Test

3 **Upload any additional documents you think may be pertinent to this protocol at Boston, Children's Hospital.**

Name	Date Last Modified	Version	Owner

There are no items to display

Title: Sample Reliance on Another IRB

Laser Device Categories

Please check the category(s) that apply to the laser devices used in this research protocols:

1
- ☐ Investigational laser device (devices not approved or cleared for marketing by the FDA)
- ☐ FDA approved laser device that has been modified/altered/reconfigured/ changed or combined

or used for an unapproved indication

☑ Laser devices that have been approved (PMA) or Cleared 510(K) by FDA and used in accordance with labeling

Title: Sample Reliance on Another IRB

Laser Devices That Have Been Approved (PMA) Or Cleared 510(K) By FDA And Used In Accordance With Labeling

1 * **List laser wavelength(s)**
laser wavelength(s)

2 * **Select the FDA-CDRH laser system classification:**

- ● **Class 1**
- ○ Class 1M
- ○ Class 2
- ○ Class 2M
- ○ Class 3B
- ○ Class 3R (previously Class 3A)
- ○ Class 4

3 **For class 3B and 4 laser system classifications:**

3.1 **List location(s) and department(s) where laser procedures will be performed.**

3.2 **List team members who will operate medical laser system.**
Note: Clinical laser operators must be credentialed by BCH before operating medical laser class 3b and 4 laser systems.

Last Name	First Name	Employee ID
There are no items to display		

Title: Sample Reliance on Another IRB

Additional Documents

1 **Please upload any additional documents if it is necessary.**

Name	Date Last Modified	Version	Owner
There are no items to display			

PI's Statement

- **I assure the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law or for authorized oversight of the research project. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity, I will seek approval by the Institutional Review Board (IRB).**
- **I assure the IRB that there are appropriate resources (funding, equipment, space, support services) to conduct this research safely and in accordance with all required human subject protection policies.**

* **The PI accepts responsibility for assuming adherence to DHHS, FDA, HIPAA and Children's Hospital's regulations and policies relative to the protection of the rights and welfare of patients/subjects participating in this study.**

● **Yes** ○ **No**

Research Team Member For BCH Employees

1 **Choose Team Member and assign priviledges.**

1.1 * **Person - Choose team member.**
Ashley Kuniholm

1.2 * **Editor - Indicate if this person should be allowed to edit the online forms, correspond with the IRB office, etc. It is recommended that one or two persons, other than the PI, are listed as Editors.**

● **Yes** ○ No

1.3 * **CC on Email Notifications - Indicate if this person should be CC'd on email notifications regarding this submission. Note: Editors receive all notifications.**

● **Yes** ○ No

2 * **Indicate the individual's role on the study.**

○ Co-Investigator

○ Research Coordinator/Assistant

○ Research Nurse

● **Admin Contact**

○ Other Research Support

If Other:
Specify:

3 * **Will the individual intervene/interact with subjects?**

○ Yes ● **No**

4 * **Will the individual obtain consent from the subject?**

○ Yes ● **No**

5 * **Will the individual review identifiable data, databases, medical records, and/or handle identifiable biological specimens?**

● **Yes** ○ No

ID: VIEW46F5B54679400
Name: Research Team Member For CHB Employees

Investigational Drug/Product

1 * **Select the type of product that will be administered that is relevant to the aims of the research protocol. If there is more than one product which is relevant to the aims of the protocol, enter information about one product at this time. You will be able to enter additional products at a later time. Do not enter drugs that are administered for clinical care and not being evaluated as part of the research aims.**

● **Drug**

○ Biologic

○ Combination

○ Other

If Combination:
Please describe:

If Other:

Please describe:

2 * **What is the generic name or descriptor of the product?**
generic name

3 **What, if any, is the commercial/trade name of the product?**
commercial/trade name

4 * **Who is the manufacturer of the product?**
manufacturer

5 * **Who is the supplier of the product?**
supplier

6 * **Who holds the IND?**

- (●) **A company, organization, NIH, consortium or university.**
- ( ) Children's Investigator
- ( ) Other

6.1 **Specify the IND number if available (if it is not available, you will need to provide the IND number prior to final IRB approval).**
IND number

6.2 * **Please specify the name of the IND holder.**
name of the IND holder

6.3 **Upload a copy of FDA IND approval correspondence, if available.**

Name	Date Last Modified	Version	Owner
IND approval correspondence.docx	4/2/2020 4:45 PM	0.01	PI Test

6.4 * **Is FDA IND approval pending?**
( ) Yes (●) **No**

7 * **What is the dosage, route of administration or application, and frequency and total duration of use of the product?**
dosage, route of administration or application, and frequency and total duration of use of the product

8 * **What is the proposed mechanism of action of the product? (Include any post-manufacturing modifications to the product expected to affect the proposed mechanism of action.)**
proposed mechanism of action of the product

9 **If there are any special issues regarding stability, please detail them here.**
any special issues regarding stability

10 **Please list any contraindications or potential drug interactions.**
any contraindications or potential drug interactions

11 **Are there any known antidotes? Please describe.**
any known antidotes

12 * **Will subjects, or their insurance providers, be charged for the investigational drug/biologic?**
( ) Yes (●) **No**

If YES:
Please upload written documentation from the FDA documenting a formal waiver for the sponsor of this research study to charge subject or their insurance providers for the investigational drug/biologic.

Name	Date Last Modified	Version	Owner

There are no items to display

13 * **Upload Investigator's Brochure and other pertinent documentation.**

Name	Date Last Modified	Version	Owner
Investigators Brochure.docx	4/2/2020 4:46 PM	0.01	PI Test

14 * **Indicate who will administer the investigational product to the subject?**
MD

RN

If Other:
Explain:

ID: VIEW470B90F6B2400
Name: Investigational Drug/Product

Investigational Devices

1 * **What is the generic name or descriptor of the device?**
generic name

2 **What is the trade name if applicable?**
trade name

3 * **Who is the manufacturer of the device?**
manufacturer

4 * **Who is the sponsor of the device trial (company, individual or entity that is responsible for conducting the study and complying with FDA sponsor responsibilities)? This may or may not be the manufacturer. Please note an investigator may hold sponsor responsibilities if it is an investigator initiated IDE (this applies to both significant and non-significant risk devices).**

- ○ A company, organization, NIH, consortium or university.
- ● **Children's Investigator**
- ○ Other

4.1 * **Please specify the Sponsor regardless of which of the above choices have been selected.**
Dr. Stafford

5 * **Who will pay for the device?**
Insurance

6 * **Is the device implanted or otherwise placed into the body?**
● **Yes** ○ No

If YES:

6.1 **Who will be responsible for the costs associated with the placement and removal of the device from the body?**
Insurance

7 * **Has the sponsor provided an investigational brochure or any other type of information about the device and previous animal or human studies?**
● **Yes** ○ No

If YES:

7.1 **Upload the information.**

Name	Date Last Modified	Version	Owner
Investigators Brochure.docx	4/2/2020 4:47 PM	0.01	PI Test

8 * **What is sponsor's risk designation for the device according to FDA definitions?**

- ● **Significant Risk (SR)**
- ○ Non Significant Risk Device (NSR)
- ○ Exempted Investigations (e.g. in vitro diagnostics, consumer preference testing)
- ○ Other Classification

8.1 ***If Significant Risk (SR), please answer the following questions.***

8.1.1 **What is the IDE number?**
IDE number

8.1.2 **Who is the IDE Sponsor?**

- ○ A company, organization, NIH, consortium or university.
- ● **Children's Investigator**

○ Other

8.1.3 Please specify the name of the IDE holder.
Dr. Stafford

8.1.4 Please upload any FDA IDE approval correspondence.

Name	Date Last Modified	Version Number	Owner
IDE approval correspondence.docx	4/2/2020 4:48 PM	0.01	PI Test

8.2 ***If Non Significant Risk, please answer the following questions.***
In order to be considered a Non Significant Risk Device (NSR) the IRB must agree with the sponsor's determination that the following conditions are applicable. Please justify how the following criteria are met.

8.2.1 The device is not intended as an implant (remaining 30 days or more in the human body) and presents a potential for serious risk to the health, safety, or welfare of a subject.

8.2.2 The device is not purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.

8.2.3 The device is not of substantial importance in diagnosing, curing, mitigating, treating, or otherwise preventing impairment of human health and does not present a potential for serious risk to the health, safety, or welfare of a subject.

8.2.4 The device does not otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

8.2.5 Who is the NSR Sponsor?

○ A company, organization, NIH, consortium or university.

○ Children's Investigator

○ Other

8.2.6 Please specify the name of the NSR Sponsor.

8.2.7 Please upload any applicable FDA correspondence.

Name	Date Last Modified	Version Number	Owner

There are no items to display

8.3 ***If Exempted Investigations, please answer the following questions:***

8.3.1 Is this a diagnostic device?

○ Yes ○ No

If YES, please justify the following criteria:

8.3.1.1 Is noninvasive

8.3.1.2 Does not require an invasive sampling procedure that presents significant risk

8.3.1.3 Does not by design or intention introduce energy into a subject

8.3.1.4 Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

8.3.2 Is this a device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution?

○ Yes ○ No

If YES:

8.3.2.1 Please explain how this study is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

8.4 ***If Other Classification:***

8.4.1 Is the device being used to investigate a basic physiological principle?

8.4.2 Is your device still something else? Please explain:

9 Please complete the following information about device control and accountability.

9.1 * How and where will the device be received from the manufacturer?
How and where will the device be received

9.2 * **Describe the location and manner in which the device will be stored?**
Location and manner in which the device will be stored

9.3 * **Who will have access to the device and how will access be controlled?**
Device access and control.

9.4 * **How will the device receipt, use and return be logged or otherwise documented?**
device receipt, use and return documentation.

10 * **How will extra devices be stored or returned to the manufacturer?**
Storage and return plan.

11 **Upload any correspondence or information available about the device risk determinations. Also attach information about the device and provide a picture if available.**

Name	Date Last Modified	Version	Owner

There are no items to display

ID: VIEW470A74B3A2000
Name: Investigational Devices

Editing Human Biological Specimen Data

1 * **Select the type of human biological specimens that will be collected as part of the protocol.**

- (●) **Blood**
- ( ) CSF
- ( ) Urine
- ( ) Sputum
- ( ) Saliva
- ( ) Tumor/Tissue
- ( ) Other

If Other:
1.1 **Specify:**

2 * **Specify the amount (if tumor/tissue, specify in g mm in 3 dimensions; if blood, CSF or urine, specify in ml).**
4ml

If Tumor/Tissue is selected, please complete questions 3-6. For all other selections, please skip questions 3-5 and answer question 6.

3 **What are the specifications?**

- (●) **Fresh**
- ( ) Sterile
- ( ) Fixed
- ( ) Other

4 **Where will the tissue be obtained?**

- [ ] Pathology
- [ ] OR
- [x] **Other BCH procedure areas**
- [ ] Outside of BCH
- [x] **Left over from research protocol**

If tissue will be obtained from Outside of BCH:
4.1 **Specify from where.**

5 **Specify the number of tissue samples to be collected.**
1

6 * **Check the appropriate category which accurately describes how and when the specimen will be obtained.**

- [x] **Prospectively collected human biological specimens obtained exclusively for research purposes during a procedure performed solely for research (muscle biopsy for research purposes).**
- [x] **Prospectively collected human biological specimens obtained exclusively for research purposes during a clinically planned procedure, (e.g., extra biopsies at endoscopy, normal skeletal muscle at surgery).**
- [x] **Excess human biological specimens obtained for clinical care, and determined to be in excess of that needed for clinical and diagnostic purposes (e.g., tumor that is leftover after pathologist's sampling has been completed, extra blood).**
- [x] **Human biological specimens that have been left over from previous research and are currently being stored.**

ID: VIEW470A295C6E400
Name: Editing Human Biological Specimen Data

Pathology Specimen Data

1 * **Specify the type of tissue/tumor. Please complete this information separately for each type of tissue.**
Surgical discards

2 * **What are the specifications?**

- (●) **Fresh**
- ( ) Sterile
- ( ) Fixed
- ( ) Other

If Other:

2.1 Specify:

3 * **Specify the amount required (if tumor/tissue, specify in g mm in 3 dimensions).**
3mm

4 * **Please justify why this amount is requested/required.**
Needed for fibroblasts.

5 * **Where will the specimen be obtained from?**

- [x] **Pathology**
- [x] **OR**
- [x] **Other BCH procedure areas**
- [ ] Outside of BCH
- [ ] Left over from research protocol

6 * **Specify the number of samples requested.**
1

7 * **What period of time are the specimens requested from?**
Next 3 years

ID: VIEW470A26EED8000
Name: Pathology Specimen Data